

REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Action, and respectfully request reconsideration of this Application in view of the above Amendment and the following remarks.

Applicants have amended Claims 1, 4, 12, 13, 33, and 37. These claims have been amended to specify that the pathogens being thermally inactivated are gram negative pathogens. Support for this amendment can be found in Example 13, which pertains to the thermal inactivation of *Escherichia coli* and *Salmonella thyphimurium*, which are both well known in the art to be gram negative pathogens. Further support for this amendment can be found in the Background, which includes numerous references to *E. coli*, a gram negative pathogen. A definition of "gram-negative" as including protobacteria such as *Escherichia coli* and *Salmonella* is attached to provide additional support. (Exhibit 1).

Applicants have also amended Claims 1, 4, 12, 13, 33, 37, and 41 to specify that the nutriment is an uncooked meat product. Support for this amendment can be found in the Background, which discusses the use of heat to kill gram negative pathogens in ground meat. See Specification, Page 2, line 25 – Page 3, line 2. Support for this amendment can also be found in Example 13, which pertains to the thermal inactivation of pathogens in ground beef.

Applicants have also cancelled Claims 3, 10, 11, 14 – 32, 35, and 43.

Pending in the application are Claims 1 – 2, 4 – 9, 12 – 13, 33 – 34, and 36 – 42.

I. Cancellation of Non-elected Claims

Applicants have cancelled Claims 14 – 32, drawn to a non-elected invention.

II. Rejections Under 35 U.S.C. §103(a)

A. Canning in view of Kemp

Claims 1 – 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Complete course in Canning p. 238, 478, 479 (“Canning”) in view of International Patent Application Publication No. WO 00/48469 in the name of Kemp et al. (“Kemp”). Applicants respectfully assert that these cited references do not teach or suggest all of the claim limitations.

Claims 1, 4, 12, 13, and 33 have been amended above to specify that a nutriment treated with the acidulant, when heated, requires about 30% to about 75% less time to inactivate 90% of any **gram negative** pathogens compared to the amount of heating time required to inactivate 90% of the **gram negative** pathogens in an untreated nutriment. These claims have also been amended to specify that the nutriment is an uncooked meat product. Neither Canning, nor Kemp, nor the combination of Canning and Kemp, teaches or suggests a method for increasing the rate of inactivation of gram negative pathogens, such as *E. coli* and *Salmonella*, by 30% to 75% in uncooked meat products.

As described in the Background, gram negative bacteria such as *E. coli* are devastating food borne pathogens often found in meat products which are resistant to traditional acidic treatments. See Specification, Page 2, lines 3 – 24, and Page 4, lines 3 – 21. These gram negative bacteria present a unique problem in the meat industry, due to the need to provide meat products to consumers in a minimally processed state which enables the consumer to cook and prepare the raw meat on his or her own. Applicants respectfully submit that methods such as sodium lactate additives, organic acid additives, freezing, and pulsed electric fields have all been demonstrated as ineffective in controlling gram negative bacteria in uncooked meat products. Applicants have enclosed two scientific abstracts in support: (1) Bolton, et al., “The ineffectiveness of organic acids, freezing and pulsed electric fields to control *Escherichia coli* O157:H7 in beef burgers,” Lett Appl Microbiol. 2002; 34(2): 139 – 43, and (2) Huang, et al., “Thermal inactivation of *Escherichia coli* O157:H7 in ground beef supplemented with sodium lactate,” J Food Prot. 2003 Apr.; 66(4): 664 – 7. (Exhibit 2 and 3 respectively).

Prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *See In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Furthermore, obvious to try, or obvious to test or experiment, is not a proper standard of 35 U.S.C. § 103. *See In re Goodwin*, 198 U.S.P.Q. 1, 3 (C.C.P.A. 1978); *In re Antoni*, 195 U.S.P.Q. 6, 8 (C.C.P.A. 1977); *In re Geiger*, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987); and *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988). Neither Canning, nor Kemp, nor the combination of Canning and Kemp suggests that traditional canning procedures can be used successfully to inactivate about 90% of gram negative bacteria in uncooked meat products in a period of time that is about 30% to about 75% less than for the untreated and uncooked meat products. The combined teaching even falls short of making suggestion to try or to experiment what is claimed here.

Canning in view of Kemp does not teach or suggest the successful use of Applicants' acidulant to reduce the necessary cooking time of uncooked meat products. Canning pertains to "artichokes, pimientos, onions, and peppers" (p. 238), "pickled cucumbers and cabbage" (p. 478), "natural dills, sweet pickles, relishes, and other processed pickle products" (p. 478), potatoes and potato salads (p. 478), and "tomatoes and various fruits" (p. 479). As described in Canning, the canning industry is concerned with the **complete sterilization** of foods, using an acidulant to shorten the time required for the **sterilization** of foods, to allow them to be **immediately eaten after storage**. See Canning, Page 238, 4th and 5th paragraphs, and Page 479, 4th full paragraph. Webster's Ninth New Collegiate Dictionary defines "sterilize" as "go free from living microorganisms." In fact, on Page 326, 2nd paragraph, Canning states the **use of aseptic procedure for canning food**. Again, Webster's Ninth New Collegiate Dictionary defines "aseptic" as "free or freed from pathogenic microorganism." While Canning's teachings may be applied to fruits, vegetables, and other pickled or canned products, which **are sterilized and ready to be eaten** immediately after storage, **in contrast**, **uncooked meat products of the present invention are not sterilized and by**

no means ready to eat, but rather are presented to the consumer in a minimally processed state to retain its original taste as much as possible. Unlike canned foods which can be stored for a relatively long period, and still will be “ready to eat,” the treated uncooked meat products of the present invention must still be cooked within a reasonable time. Thus, the teachings of Canning cannot be applied to uncooked meat products to demonstrate a reasonable expectation of success in inactivating gram negative bacteria.

In addition, the references in combination do not teach or suggest a 30% to 75% reduction in the amount of time required to inactivate 90% of the gram negative pathogens. The Examiner has stated that “heating to inactivate 90% of the pathogens in a particular length of time is ages old in canning” and that “it would have been obvious to heat a nutriment for a particular length of time in order to kill a particular amount of pathogens.” See Final Office Action, pages 2 – 3. However, Applicants respectfully submit that the Examiner has failed to consider the significance of the “particular length of time” within Applicant’s claims. **Applicant’s claimed method inactivates 90% of gram negative pathogens in 30% to 75% less time during the heating of the meat products.** This reduction in necessary heating time is vitally important to the meat industry, due to the constant threat of consumption of undercooked meat. As stated in the Background, many consumers do not realize that ground beef will brown before gram negative bacteria is killed. See Specification, Page 2, line 28 – Page 3, line 2. Furthermore, a reduction in necessary heating time enables the consumer to preserve the flavor of the meat product by avoiding overcooking. **A decrease or reduction in necessary heating time is a significant advantage in the meat industry, yet it is not taught or suggested with regard to the sterilized and ready to eat foods of the canning industry.**

For these reasons, Applicants respectfully submit that Claims 1, 2, 4 – 9, 12, 13, 33, 34, and 36 are patentable over Canning in view of Kemp.

B. Kemp in view of Guthery

Claims 37 – 43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kemp in view of Guthery. Applicants respectfully assert that these cited references do not teach or suggest all

of the claim limitations and that the cited references do not suggest a reasonable expectation of success.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Guthery does not teach or suggest all of the claim limitations because Guthery does not teach or suggest a step of heating a nutriment to achieve thermal inactivation. Guthery is concerned with "provid[ing] improved compositions and methods for treating poultry and other animal carcasses to eradicate Salmonella and other bacteria from the carcass surface" (emphasis added). See Guthery, Col. 3, lines 37 – 40. Thus, Guthery does not teach the claimed method of using acidulation to reduce the length of time a consumer must cook a meat product in order to inactivate pathogens.

Furthermore, Guthery does not teach or suggest using acidulation to achieve a significant 30% to 75% reduction in necessary heating times for meat products. The Examiner has stated that "it would have been obvious to heat for the particular claimed amount since it is known to calculate the thermal date of pathogens as shown by Canning." See Final Office Action, page 3. However, Applicant respectfully submits that the Examiner has failed to consider the significance of the "particular length of time" within Applicant's claims. **Applicant's claimed method inactivates 90% of gram negative pathogens in 30% to 75% less time during the heating of the meat products.** As discussed above, the reduction of necessary heating time is of vital importance in the meat industry. Guthery is concerned with carcass processing, not cooking times.

Finally, there is no teaching or suggestion in Guthery that contact with an acidulant will increase the rate of thermal inactivation of gram negative pathogens throughout the nutriment material as it is heated by a consumer. Guthery's examples demonstrate some eradication of bacteria from the surface of the animal carcass only. See Guthery, Col. 3, line 40. In addition, Guthery teaches that the acidulant should be rinsed from the animal carcass after treatment. See Guthery, Col. 6, lines 33 – 35. Thus, Guthery does not address the treatment of any types of

uncooked meat products as they are received and cooked by a consumer. Eradication of bacteria from the surface of an animal carcass during standard industry processing does not teach or suggest the use of an acidulant to reduce necessary cooking times by consumers.

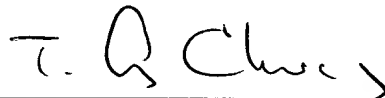
For these reasons, Applicants respectfully submit that Claims 37 – 43 are patentable over Kemp in view of Guthery.

IV. Conclusion

Applicants respectfully submit that, in light of the foregoing comments, Claims 1, 2, 4 – 9, 12, 13, 33, 34, and 36 – 42 are in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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